

# NOSB COMMITTEE RECOMMENDATION

Form NOPLIST1. Committee Transmittal to NOSB

For NOSB Meeting: <u>May 2008</u>	Substance: <u>Rehmannia Root Powdered Extract</u>																								
Committee: Crops <input type="checkbox"/> Livestock <input type="checkbox"/> Handling <input checked="" type="checkbox"/> Petition is for: <u>Inclusion of Rehmannia Root Powdered Extract on the National List § 205.606</u>																									
<b>A. Evaluation Criteria</b> (Applicability noted for each category; Documentation attached) <span style="float: right;"><b>Criteria Satisfied? (see B below)</b></span>																									
1. Impact on Humans and Environment	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/>																								
2. Essential & Availability Criteria	Yes <input type="checkbox"/> No <input type="checkbox"/> N/A <input checked="" type="checkbox"/>																								
3. Compatibility & Consistency	Yes <input type="checkbox"/> No <input type="checkbox"/> N/A <input checked="" type="checkbox"/>																								
4. Commercial Supply is Fragile or Potentially Unavailable as Organic (only for 606)	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> N/A <input type="checkbox"/>																								
<b>B. Substance Fails Criteria Category:</b> 4      Comments: <u>The petition is not compelling in it's assertion that this material cannot be obtained organically in the appropriate form, quantity, or quality.</u>																									
<b>C. Proposed Annotation (if any):</b> _____ Basis for annotation: To meet criteria above: _____ Other regulatory criteria: _____ Citation: _____																									
<b>D. Recommended Committee Action &amp; Vote (State Actual Motion):</b> <u>Recommend Rehmannia Root Powdered Extract for listing on §205.606</u>																									
Motion by: <u>Julie Weisman</u> Seconded: <u>Steve DeMuri</u> Yes: <u>0</u> No: <u>5</u> Absent: <u>1</u> Abstain: <u>0</u>																									
<table border="1" style="border-collapse: collapse; width: 100%;"> <tr> <td style="width: 25%;">Crops</td> <td style="width: 25%;"></td> <td style="width: 25%;">Agricultural</td> <td style="width: 25%; text-align: center;"><input checked="" type="checkbox"/></td> <td style="width: 25%;">Allowed<sup>1</sup></td> <td style="width: 25%;"></td> </tr> <tr> <td>Livestock</td> <td></td> <td>Non-Synthetic</td> <td></td> <td>Prohibited<sup>2</sup></td> <td></td> </tr> <tr> <td>Handling</td> <td style="text-align: center;"><input checked="" type="checkbox"/></td> <td>Synthetic</td> <td></td> <td>Rejected<sup>3</sup></td> <td style="text-align: center;"><input checked="" type="checkbox"/></td> </tr> <tr> <td>No restriction</td> <td></td> <td>Commercially Un-Available as Organic<sup>1</sup></td> <td></td> <td>Deferred<sup>4</sup></td> <td></td> </tr> </table>	Crops		Agricultural	<input checked="" type="checkbox"/>	Allowed <sup>1</sup>		Livestock		Non-Synthetic		Prohibited <sup>2</sup>		Handling	<input checked="" type="checkbox"/>	Synthetic		Rejected <sup>3</sup>	<input checked="" type="checkbox"/>	No restriction		Commercially Un-Available as Organic <sup>1</sup>		Deferred <sup>4</sup>		
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1) Substance voted to be added as "allowed" on National List to § 205. _____ with Annotation (if any) _____ _____																									
2) Substance to be added as "prohibited" on National List to § 205. _____ with Annotation (if any) _____ _____ Describe why a prohibited substance: _____ _____																									
3) Substance was rejected by vote for amending National List to § 205. 606      Describe why material was rejected: <u>Material was rejected because petition did not demonstrate that this material may not be available in organic form.</u>																									
4) Substance was recommended to be deferred because _____ _____ If follow-up needed, who will follow up _____																									
<b>E. Approved by Committee Chair to transmit to NOSB:</b>																									
<u>Julie Weisman</u> Committee Chair	<u>3/13/2008</u> Date																								

**NOSB EVALUATION CRITERIA FOR SUBSTANCES ADDED TO THE NATIONAL LIST**

**Category 1. Adverse impacts on humans or the environment? Substance - Rehmannia Root Powdered Extract**

Question	Yes	No	N/A <sup>1</sup>	Documentation (TAP; petition; regulatory agency; other)
1. Are there adverse effects on environment from manufacture, use, or disposal? [§205.600 b.2]		X		Pages 2 and 3 of the petition claim there are no adverse effects on the environment.
2. Is there environmental contamination during manufacture, use, misuse, or disposal? [§6518 m.3]		X		Same as above
3. Is the substance harmful to the environment? [§6517c(1)(A)(i);6517(c)(2)(A)i]		X		Same as above
4. Does the substance contain List 1, 2, or 3 inerts? [§6517 c (1)(B)(ii); 205.601(m)2]		X		None listed in the petition, ingredient specification, or MSDS.
5. Is there potential for detrimental chemical interaction with other materials used? [§6518 m.1]		X		Page 2 of the petition
6. Are there adverse biological and chemical interactions in agro-ecosystem? [§6518 m.5]		X		None indicated in the petition - pages 2 and 3.
7. Are there detrimental physiological effects on soil organisms, crops, or livestock? [§6518 m.5]		X		Page 3 of the petition.
8. Is there a toxic or other adverse action of the material or its breakdown products? [§6518 m.2]		X		Pages 2 and 3 of the petition.
9. Is there undesirable persistence or concentration of the material or breakdown products in environment?[§6518 m.2]		X		Same as above
10. Is there any harmful effect on human health? [§6517 c (1)(A)(i) ; 6517 c(2)(A)i; §6518 m.4]		X		Petition page 3 Section 9 d.) states that Rehmannia Root has been used as an herbal medicine for thousands of years in China. Petitioner claims it was marketed in the US prior to 10/15/94, and was grandfathered in as “considered safe” per DSHEA, upon it’s implementation on 10/15/94.
11. Is there an adverse effect on human health as defined by applicable Federal regulations? [205.600 b.3]		X		See above
12. Is the substance GRAS when used according to FDA’s good manufacturing practices? [§205.600 b.5]		X		Page 3 of petition - Rehmannia Root powdered extract was marketed in the U.S. prior to October 15, 1994. The Dietary Supplement Health and Education Act (DSHEA) provides that supplement ingredients that were marketed in the U.S. prior to the enactment of DSHEA on October 15, 1994 are considered safe and are “grandfathered in” as safe for use. This herb is also listed in The American Herbal Products Association’s Herbs of Commerce, 2nd Edition.
13. Does the substance contain residues of heavy metals or other contaminants in excess of FDA tolerances? [§205.600 b.5]		X		None listed in the MSDS attached to the petition.

<sup>1</sup>If the substance under review is for crops or livestock production, all of the questions from 205.600 (b) are N/A—not applicable.

**Category 2. Is the Substance Essential for Organic Production? Substance - Rehmannia Root Powdered Extract**

Question	Yes	No	N/A <sup>1</sup>	Documentation (TAP; petition; regulatory agency; other)
1. Is the substance formulated or manufactured by a chemical process? [6502 (21)]		X		Page 2 of petition states the root is harvested, dried, clean milled and placed into an extraction kettle. Water and ethanol are added and heat applied. The extracted liquid is concentrated into essential oils and standardized to the desired concentration. The essential oils are mixed with organic astragalus root carrier then spray dried and ground into a powder.”
2. Is the substance formulated or manufactured by a process that chemically changes a substance extracted from naturally occurring plant, animal, or mineral, sources? [6502 (21)]		X		See above
3. Is the substance created by naturally occurring biological processes? [6502 (21)]			X	This is an agricultural product
4. Is there a natural source of the substance? [§205.600 b.1]			X	This is an agricultural product
5. Is there an organic substitute? [§205.600 b.1]			X	Material is being petitioned for inclusion on §205.606; see category 4 below.
6. Is the substance essential for handling of organically produced agricultural products? [§205.600 b.6]			X	This is an agricultural product
7. Is there a wholly natural substitute product? [§6517 c (1)(A)(ii)]			X	This is an agricultural product
8. Is the substance used in handling, not synthetic, but not organically produced? [§6517 c (1)(B)(iii)]	X			This is an agricultural product being petitioned for inclusion on §205.606..
9. Is there any alternative substances? [§6518 m.6]			X	
10. Is there another practice that would make the substance unnecessary? [§6518 m.6]			X	

<sup>1</sup>If the substance under review is for crops or livestock production, all of the questions from 205.600 (b) are N/A—not applicable.

**Category 3. Is the substance compatible with organic production practices? Substance - Rehmannia Root  
Powdered Extract**

Question	Yes	No	N/A <sup>1</sup>	Documentation (TAP; petition; regulatory agency; other)
1. Is the substance compatible with organic handling? [§205.600 b.2]			X	
2. Is the substance consistent with organic farming and handling? [§6517 c (1)(A)(iii); 6517 c (2)(A)(ii)]			X	
3. Is the substance compatible with a system of sustainable agriculture? [§6518 m.7]			X	
4. Is the nutritional quality of the food maintained with the substance? [§205.600 b.3]			X	
5. Is the primary use as a preservative? [§205.600 b.4]		X		
6. Is the primary use to recreate or improve flavors, colors, textures, or nutritive values lost in processing (except when required by law, e.g., vitamin D in milk)? [205.600 b.4]		X		
7. Is the substance used in production, and does it contain an active synthetic ingredient in the following categories:		X		
a. copper and sulfur compounds;		X		
b. toxins derived from bacteria;		X		
c. pheromones, soaps, horticultural oils, fish emulsions, treated seed, vitamins and minerals?		X		
d. livestock parasiticides and medicines?		X		
e. production aids including netting, tree wraps and seals, insect traps, sticky barriers, row covers, and equipment cleaners?		X		

<sup>1</sup>If the substance under review is for crops or livestock production, all of the questions from 205.600 (b) are N/A—not applicable.

**Category 4. Is the commercial supply of an agricultural substance as organic, fragile or potentially unavailable?** [§6610, 6518, 6519, 205.2, 205.105 (d), 205.600 (c) 205.2, 205.105 (d), 205.600 (c)]

**Substance - Rehmannia Root Powdered Extract**

Question	Yes	No	N/A	Comments on Information Provided (sufficient, plausible, reasonable, thorough, complete, unknown)
1. <u>Is the comparative description provided</u> as to why the non-organic form of the material /substance is necessary for use in organic handling?		X		Petition did not provide sufficient information explaining why the non-organic form of the material is necessary for use in organic handling
2. Does the current and historical industry information, research, or evidence provided explain how or why the material /substance cannot be obtained organically in the appropriate <b>form</b> to fulfill an essential function in a system of organic handling?		X		Petition page 4 Section 12. states petitioner's procurement department is continuously searching for organic forms of the non-organic ingredients used in the company's formulations. Regular searches include monthly review of trade journals, ingredient source contacts, internet searches, and websites of both the Organic Trade Association and Quality Assurance International. There is no detail provided as to who and when potential sources were contacted, and to what extent the root was unavailable in quality, quantity, or form. An internet search indicated that organic rehmannia root in some quantity was available.
3. Does the current and historical industry information, research, or evidence provided explain how or why the material /substance cannot be obtained organically in the appropriate <b>quality</b> to fulfill an essential function in a system of organic handling?		X		See above
4. Does the current and historical industry information, research, or evidence provided explain how or why the material /substance cannot be obtained organically in the appropriate <b>quantity</b> to fulfill an essential function in a system of organic handling?		X		See above
5. Does the industry information provided on material / substance non-availability as organic, include ( but not limited to) the following: a. Regions of production (including factors such as climate and number of regions);		X		Page 2 Section 5 of the petition describes historical producing areas, but does not address the current situation, nor does it discuss supplies related to hurricanes, floods, droughts, trade related issues, etc.
b. Number of suppliers and amount produced;		X		See above
c. Current and historical supplies related to weather events such as hurricanes, floods, and droughts that may temporarily halt production or destroy crops or supplies;		X		See above
d. Trade-related issues such as evidence of hoarding, war, trade barriers, or civil unrest that may temporarily restrict supplies; or		X		See above
e. Are there other issues which may present a challenge to a consistent supply?		X		See above